

PATENT

Docket No. 1377-0137P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: John Kevin Collins *et al.*
APPLN. NO.: 09/367,105 GROUP: 1651
FILED: November 10, 1999 EXAMINER: I. Marx
FOR: PROBIOTIC STRAINS FROM
LACTOBACILLUS SALIVARIUS AND
ANTIMICROBIAL AGENTS OBTAINED
THEREFROM

DECLARATION UNDER 37 C.F.R. § 1.32

Assistant Commissioner of Patents
Washington, DC 20231

Sir:

I, John Bienenstock, a Canadian citizen, of Departments of Medicine, Pathology and Molecular Medicine, McMaster University, 1200 Main Street West, Rm 3N26, Hamilton, ON, L8S 3Z5, Canada. I have taken early retirement from the University, however, I hold an honorific title which is "University Professor" that entitles me to a life-time appointment and full privileges of retaining my research and other activities. I am still a Professor of Medicine, Pathology and Molecular Medicine. My *Curriculum Vitae* is attached hereto. I do solemnly and sincerely declare as follows:

1. I have read the Office Action dated June 19, 2001, each of the three cited references and a copy of the specification of the above U.S. Application.

2. I have also read a draft of the Declaration to be made by Dr. Liam O'Mahony by way of response and I fully agree with the statements contained in that Declaration as regards the cited references relied on by the Examiner.
3. In my view that novel and inventive approach taken by Collins *et al.* to isolate *Lactobacillus salivarius* strains with potential application to human healthcare was unprecedented.
4. The stains of *Lactobacillus salivarius* isolated by Collins *et al.* from appendices and sections of the large and small intestine of the human gastrointestinal tract obtained during reconstructive surgery represents a significant departure from previous methods for isolating probiotic bacteria.

I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Dec 10 '01
Date

John Bienenstock
John Bienenstock

PROFESSOR JOHN BIENENS . CK
Biographical Sketch

St. Paul's School, London, U.K.	
M.B.B.S.	1960
King's College, London University and Westminster Hospital Medical School, London, U.K.	
M.R.C.P.	1964
F.R.C.P.(C)	1976
F.R.C.P.	1980
F.R.S.(C)	1992
M.D. (Honoris Causa), Göteborg, Sweden	1998

Summary of Accomplishments

John Bienenstock is an internationally known physician and scientist and a Fellow of the Royal Society of Canada. He received his internal medicine training in various teaching hospitals in London, UK. In 1964, he went to Boston on a USPHS Fellowship and worked in the Lovett Memorial Group at the Massachusetts General Hospital with Dr. Kurt Bloch. He acted clinically as a rheumatologist while studying immunology in association with, amongst others, Dr. Frank Austen. In 1966, Dr. Bienenstock went to the State University of New York at Buffalo to take up an appointment with Dr. Tom Tomasi to work on mucosal immunology. Here, he acted from a clinical point of view as a consultant on the wards in internal medicine, and pursued his research. He received a Buswell Fellowship and became an Assistant Research Professor in Medicine. In 1968, he went to McMaster University, where he has been ever since, pursuing a clinical, research and administrative career.

At McMaster, from an administrative point of view, he was the first Chair of the Committee on Scientific Development, the forerunner of the current Associate Dean, Research position. In this role, he oversaw the early development of multi-disciplinary research programmes, the distribution of space according to research function and the early developments of research at McMaster in the Faculty of Medicine.

From 1971 to 1978 he was the founding Director of the Host Resistance Programme, a multi-disciplinary research program involving immunology and virology. He became Chair of the Department of Pathology in 1978 and from this time until he stepped down in 1989, he oversaw major development and expansion of this department into the premier basic science department in the Faculty, and one of the best in the world.

Dr. Bienenstock is a clinical immunologist and administered the development of the Clinical Immunology programme at McMaster, which has Royal College accreditation. He was responsible as Chair of Pathology for the maintenance and development of the Regional Laboratory Programme, a unique, co-ordinated laboratory programme which provides laboratory diagnostic services including clinical chemistry, hematology, anatomic pathology and microbiology for the six sites of the two teaching hospitals in the Hamilton-Wentworth Region.

In 1989, he became the Vice-President for Health Sciences and in 1992 undertook the role of the Dean and Vice-President Health Sciences, a Faculty which expanded to include medicine, occupational and physiotherapy, nursing, midwifery and graduate studies. He stepped down

from these positions . 1997 at which time the overall budget \$125 million. During his tenure as Dean, he served as Chair of the Council of Ontario Faculties of Medicine. He oversaw an expansion of the role of the Faculty in healthcare, improved the research position in terms of international acclaim, introduced Midwifery, Physiotherapy and Occupational Therapy into the Faculty's educational and research programs, and gained approval of the government to fund a \$30 million building development to house the Institute of Applied Health Sciences, a joint program between the Faculty and Mohawk College. Most recently he was responsible for awards of \$22 million from the Canadian Foundation for Innovation towards the cost of several large research infrastructure projects in mental health, respirology and molecular biology which include major equipment and construction. The total package for this with matching funds from St. Joseph's Hospital and the Province of Ontario was over \$50 million.

From a research standpoint, Dr. Bienenstock held a continuous operating research grant from the Medical Research Council of Canada from 1968 to 1999. He has published more than 380 peer reviewed articles and other publications. He has authored, edited and co-edited several books including the standard text on mucosal immunology, now in its second edition. He is known best for his work in mucosal immunity in which he pioneered the concept of a common mucosal immune system and developed the first full description of bronchus associated lymphoid tissue and its involvement in the mucosa associated lymphoid tissue system of the body. His more recent work has related to an elucidation of mechanisms of allergy, mucosal immunology, and most particularly, the interactions between mast cells and other cells of the immune system with the nervous system.

Dr. Bienenstock is a frequent speaker at symposia and plenary sessions around the globe and has organized a number of successful international conferences on a wide variety of subjects. He has served as President of the Canadian Society of Immunology, the International Society for Mucosal Immunology and is currently the President of the Collegium Internationale Allergologicum. He acts regularly as an external consultant to public sectors, and in this capacity was invited by the Government of Australia to review the complete operation of the National Health and Medical Research Council. This resulted in the overhaul and restructuring of the Council's organization and operations. He has similarly reviewed the research operations of the Universities of Sydney, Australia, and Göteborg, Sweden and recently (2000), completed a review of Public Health for the Karolinska Institute, Stockholm, Sweden. He acts as a consultant to venture capital groups, foundations and especially the pharmaceutical industry in his area of expertise. He chairs the Scientific Advisory Board of International Medical Innovations, Inc and a new Western Australian Biotechnology startup, Vasse Research. He serves on the Board of ProMetic Life Sciences, Inc. and was the founder of two companies in the Biotechnology Sector. He acted from 1996-99 as Chief Scientific Officer for a UK based company, OraTol Inc., involved in oral immunotherapeutic approaches to allergy and asthma.

Dr. Bienenstock has served in a voluntary capacity on a number of Boards, including that of the Canadian Red Cross Society who awarded him the order of the Red Cross in 1990. He was also Chair of the Board of the Dundas Valley School of Art, on the Board of the Hamilton Art Gallery and is an accomplished artist and a member of the Society of Canadian Artists. He received the Finkelstein Prize from the Crohn's and Colitis Foundation of Canada in 1996 and was accorded the honour of University Professor in 1997 by McMaster University, and an MD degree (Honoris Causa) by the University of Göteborg, Sweden in 1998.